UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

MONROE DIVISION

BRYANT LYLES	**CIVIL ACTION NO. 15-0910**
VERSUS	**JUDGE ROBERT G. JAMES**
MEDTRONIC, INC., ET AL.	**MAG. JUDGE JOSEPH PEREZ-MONTES**

RULING

Pending before the Court is Plaintiff Bryant Lyles' ("Lyles") Motion for Relief from Judgment [Doc. No. 107]. Lyles asserts that the Court should set aside its judgment of dismissal, re-open this case, and allow him to amend his complaint for a fourth time to assert claims against Defendant Medtronic Sofamor Danek USA ("MSD") under the Louisiana Products Liability Act ("LPLA") for failure to warn and defective design of its product, the Verte-Stack Anatomic PEEK ("Verte-Stack"), also known as the Verte-Stack Spinal System. MSD opposes the motion. The motion has been fully briefed, and oral argument has been held.

For the following reasons, Lyles' motion is DENIED.

I. FACTUAL AND PROCEDURAL BACKGROUND[1]

On May 9, 2013, Lyles was admitted to LSU Health Sciences Center Shreveport ("LSUHSC") with complaints of neck and bilateral upper extremity pain, difficulty walking, and complaints of falling and dropping things out of his hands. Lyles had an ataxic gait. An MRI was performed that day and showed severe stenosis behind the C5 body, as well as C4-C5 and C5-C6

[1]A more complete statement of facts is contained in the record. The Court limits its review of the facts to those pertinent to the pending motion.

disc spaces. Lyles suffered from severe progressive myelopathy with stenosis.

The following day, May 10, 2013, Dr. Anthony Sin performed surgery on Lyles to relieve pressure on his spinal cord. During surgery, Dr. Sin removed the C5 vertebral body, a procedure known as an anterior corpectomy. Dr. Sin also removed bone spurs and disc material between the disc spaces C4 and C5 and C5 and C6.

Dr. Sin then inserted the Verte-Stack, a vertebral body replacement device, into the C5 cavity to replace the C5 bone that had been removed. Additionally, Dr. Sin inserted Progenix, a putty-like bone graft material, mixed with bone dust from the bone and bone spurs which had been removed from Lyles' spine. Dr. Sin also attached an Atlantis Translational Anterior Cervical Plate System ("Atlantis Plate") to the C4 and C6 vertebrae using four screws. The Atlantis Plate is used as a temporary aid to fusion and to help stabilize the anterior cervical spine during spinal fusions in patients with degenerative disc disease. The Atlantis Plate consists of two separate metal components which are joined by a track and runner system to form one plate.

One notation in Lyles' medical record also indicated that the Infuse Bone Graft Device ("Infuse") had been used in his surgery, although Lyles was not billed for this device, and Dr. Sin denied that it was used. Infuse is a bio-engineered bone protein and collagen sponge that is contained in a cage-like device and placed in the spine (vertical column) with the hope that the protein will cause the adjacent vertebrae to grow over the cage and fuse into a solid bone mass.

The Verte-Stack, Progenix, Atlantis Plate, and Infuse are all products manufactured by MSD or its parent company, Medtronic, Inc. ("Medtronic").[2]

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[2]It appears from the record that all the products were manufactured by MSD, but it is not entirely clear. Out of an abundance of caution, the Court refers to both entities.

Lyles was discharged from LSUHSC on May 14, 2013, but returned six days later with complaints that ultimately resulted in a second surgery. On February 6, 2014, Dr. Sin performed a posterior decompressive cervical laminectomy at C4-C6, followed by insertion of rods and set screws for arthrodesis of C3-C6.

Dr. Sin did not perform any further anterior surgery, and both the Verte-Stack and the Atlantis Plate remain in or attached to Lyles' spine.

Lyles has continued to suffer significant back and neck problems since his surgeries.

On January 12, 2015, Lyles' counsel requested that a medical review panel be convened to consider the actions/inactions of LSUHSC and Dr. Sin. [Doc. No. 90, Exhibit 1]. At that time, Lyles contended that a "titanium plate was fused to his spine" and that this "plate implanted in his body had cracked." *Id.*

On February 10, 2015, Lyles filed suit against Medtronic in the Fifth Judicial District Court, Parish of Franklin, State of Louisiana. In his original state court Petition, Lyles alleged that Medtronic manufactured "an internal orthopedic device" that was "installed on . . . Lyles' spinal column" and that the device was defective and unreasonably dangerous in construction, composition, and design. [Doc. No. 1].

Early in this litigation, between January and February 2015, Lyles received medical records, including the surgical implant log. These records identify "Medtronic" as the manufacturer of the products used except for Progenix. [Doc. No. 45-2, pp. 10-12];[Doc. No. 107-3]. As Lyles points out, Verte-Stack is not identified by name, but it is identified as an anatomic implant manufactured by Medtronic. No manufacturer is listed for Progenix, but it *is* clearly identified by name as a product that was used in Lyles' surgery.

On March 26, 2015, Medtronic removed the case to this Court.

On April 29, 2015, Medtronic filed a Motion to Dismiss [Doc. No. 9]. In that motion, Medtronic argued that Lyles' claims under the Louisiana Products Liability Act ("LPLA"), LA. REV. STAT. § 2800.51, *et seq.*, were prescribed on the fact of his Petition. The LPLA has a one-year prescriptive period, and Lyles' Petition was filed more than one year after images were taken of his spinal column and by which "physicians determined 'that the device manufactured by Medtronic had failed,' and for that reason he underwent surgery on February 6, 2014, 'to repair the malfunctioning device.'" [Doc. No. 9, p. 2 (quoting [Doc. No. 1, ¶ 9])].

On May 5, 2015, Lyles moved to amend his Complaint. Then-Magistrate Judge James D. Kirk granted the motion, and the Amended Complaint was filed on May 8, 2015. [Doc. No. 13]. In the Amended Complaint, Lyles again asserted that the "internal orthopedic device" manufactured by Medtronic failed, but further alleged that "[f]ailure of the device was not diagnosed until Lyles' final discharge diagnosis" on February 14, 2014. [Doc. No. 13, ¶ 9]. Lyles further alleged that Medtronic had a duty to ensure that the device was not unreasonably dangerous in its construction, composition, and design for its reasonable and expected use, but that the device contained an unreasonably dangerous condition which was in existence at the time the device left Medtronic's control. Finally, Lyles alleged that Medtronic's breach of its duty was a proximate cause of the damage he incurred.

On May 27, 2015, counsel for MSD forwarded the report of its expert, Dr. Hallett Mathews, to Lyles' counsel via overnight express delivery. Dr. Mathews' report identified the Verte-Stack implant in at least four places.

On May 28, 2015, Lyles issued discovery requests. In Request for Production No. 5, Lyles

requested "[a]ll information retained by Medtronic concerning the medical devices implanted in Bryant Lyles' spine on May 10, 2013 including date of design, manufacture, sale and all information required to be retained by Medtronic pursuant to 21 CFR 821.25." [Doc. No. 107, Exh. 4]. In Interrogatory No. 2, Lyles asked MSD to "[i]dentify any and all devices or products manufactured or sold by Medtronic which were used on Bryant Lyles at any time." [Doc. No. 107, Exh. 4].

On June 10, 2015, Lyles again moved to amend his complaint. The motion was again granted, and Lyles' Second Amended Complaint [Doc. No. 17] was filed on June 11, 2015. In the Second Amended Complaint, Lyles substituted MSD for Metronic as Defendant. He again referred to the "internal orthopedic device manufactured" by MSD, but he added a claim against MSD based on the alleged use of "a product manufactured by [MSD] called Infuse." *Id.* at ¶ 3. Lyles explained that MSD "is in the business of manufacturing internal orthopedic devices, such as the one installed on Mr. Lyles' spine . . . as well as bone graft substitutes." *Id.* at ¶ 4. In paragraphs 15-21 of the Second Amended Complaint, Lyles made further factual allegations and asserted claims against MSD based on the alleged use of Infuse.

On June 24, 2015, MSD filed a Motion to Dismiss Plaintiff's Second Amended Complaint. [Doc. No. 20], arguing that Lyles' claims against it with respect to Infuse are preempted by the Medical Devices Amendments of 1976, 21 U.S.C. § 360k(a), as interpreted by the Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). MSD argued further that Lyles' claims "whether addressed at the Infuse Device or the Atlantis Plate" are insufficient as a matter of law because they "lack any factual allegations that rise above anything more than pure speculation and conjecture as to any product defect or causation." *Id.*

On July 14, 2015, Lyles filed an opposition memorandum to MSD's Motion to Dismiss

Plaintiff's Second Amended Complaint. [Doc. No. 25]. Lyles also attempted to file another amended complaint without leave of court, but the Clerk of Court issued a deficiency notice to him. In his opposition memorandum, Lyles argued that his proposed third amended complaint had been drafted to include "causes of action for fraud and violations of the Louisiana Unfair and Deceptive Trade Practices Act [LUPTA] which are not expressly or impliedly preempted" and to include "additional facts sufficient to state causes of action under fraud, the [LUPTA], and the [LPLA]." *Id.* Accordingly, he argued that MSD's motion should be denied as moot.

The following day, Lyles corrected the deficiency by filing a Motion for Leave to File Third Amended Complaint [Doc. No. 27], which Magistrate Judge Kirk granted.[Doc. No. 28] on July 16, 2015. In his Third Amended Complaint, Lyles added Medtronic back as a Defendant and retained MSD as a Defendant as well. He alleged that both Defendants embarked on a marketing campaign to provide false and misleading information concerning the safety and effectiveness of Infuse, detailing specific facts in support of this claim. He continued to assert LPLA claims against MSD "as the manufacturer of the **anterior plate** installed in plaintiff's back." *Id.* at ¶62 (emphasis added).

On July 28, 2015, Magistrate Judge Kirk issued an electronic order indicating that MSD's June 24, 2015 Motion to Dismiss [Doc. No. 20] had been mooted by the filing of the Third Amended Complaint, but inviting MSD and Medtronic to file another motion if appropriate. [Doc. No. 30].

On July 30, 2015, MSD filed a Motion to Dismiss Lyles' Third Amended Complaint and Request for Judicial Notice [Doc. No. 31]. In the latest dispositive motion, MSD argued that (1) the LUPTA and intentional fraud claims related to Infuse fail because the LPLA provides the exclusive remedy for claims against a product manufacturer, (2) the Infuse claims are expressly or impliedly preempted, and (3) the Atlantis Plate and Infuse claims are insufficient as a matter of law.

Finally, MSD moved the Court to take judicial notice of certain documents in support of its motion.

Separately, but on the same date, Medtronic filed a Motion to Dismiss Lyles' Third Amended Complaint [Doc. No. 32]. Medtronic moved to dismiss Lyles' Third Amended Complaint for the reasons stated in MSD's motion, but also on the separate ground that the claims against it are time barred.

Lyles opposed the motions to dismiss. In his memorandum responding to the MSD motion, Lyles' arguments were limited to the Atlantis Plate and Infuse products. Lyles clearly identified the Atlantis Plate as the "defective or unreasonably dangerous" MSD product that was "installed on May 10, 2013," and which allegedly failed and caused a second surgery. [Doc. No. 37, pp. 21-22]. Likewise, in his memorandum responding to the Medtronic motion, Lyles raised arguments relating to the Infuse product. [Doc. No. 38].

Medtronic and MSD, respectively, filed reply memoranda in support of their motions to dismiss. [Doc. Nos. 40 & 41].

On August 17, 2015, Lyles' counsel took the depositions of Dr. Sin and Dr. Shihao Zhang, a surgeon who assisted during Lyles' surgery. Both were questioned about their use of the Verte-Stack implant and Progenix. At beginning of Dr. Sin's deposition, MSD's counsel told Dr. Sin that MSD was the manufacturer of the Verte-Stack implant. [Doc. 45-3, p. 66]. During that deposition, the term "Verte-Stack" was used several times. *Id.* at pp. 66, 71, 74, 77, 80 & 86. Dr. Sin also explained his use of Progenix and explicitly referred to it several times. *Id.* at pp. 67, 69, 70, 77 & 78. Finally, Dr. Sin testified that the Verte-Stack did not migrate, was not displaced, remained functioning, and that it did not cause injury to Lyles. *Id.* at p. 80.

Dr. Zhang was also asked about a "cage" that was installed during Lyles' surgery and was

asked if it was a "Verte-Stack Peek implant," although he did not specifically recall what type of Peek implant it was. [Doc. No. 45-4, p. 77]. He specifically identified Progenix as being used, explained what it was, where it was inserted, and that it is manufactured by Medtronic. *Id.* at p. 79.

On September 30, 2015, MSD responded to Lyles' May 28, 2015 discovery responses. First, MSD raised a general objection to discovery regarding Infuse "because the operative report and implant record of LSUS-HS, the hospital at which Plaintiff underwent surgery, establish that Infuse was not used . . . and because Dr. Anthony Sin, Plaintiff's surgeon, testified under oath" that it was not used. [Doc. No. 107, Exh. 4]. In its specific response to Lyles' Request for Production No. 5, MSD stated:

> The [Atlantis Plate] is exempt from 21 CFR part 821, because it is not a "life sustaining device."
>
> Without lot or batch number, MSD cannot provide specific manufacture or sale date of the [Atlantis Plate] implanted in plaintiff.
>
> See attached documents labeled MSD 19-23, relating to the [Atlantis Plate].

[Doc. No. 107, Exh. 4]. MSD did not object to providing information concerning the Verte-Stack, nor did it provide any information on Verte-Stack. Further, to the extent that Progenix is a medical "device," rather than a product, MSD did not object to providing information concerning Progenix nor did it provide any information on Progenix.

MSD responded to Lyles' Interrogatory No. 2 by stating that

> [t]he Medtronic devices used on Bryant K. Lyles are identified in the records of LSU-University Health Shreveport, the hospital at which Plaintiff underwent surgery. Attached are page 30 of the hospital's records, being the Implant Record for May 10, 2013, and page 513, being the Implant Record for February 6, 2014.

[Doc. No. 107, Exh. 4].

On October 20, 2015, Lyles moved for an extension of the discovery deadline. Defendants opposed that motion. On October 22, 2015, Magistrate Judge Kirk granted the motion in part and denied it in part. [Doc. No. 44]. Among other extensions, Magistrate Judge Kirk extended the discovery deadline until December 24, 2015.

On October 29, 2015, Defendants filed a Motion for Partial Summary Judgment [Doc. No. 45], contending that Infuse was not implanted or used during the May 10, 2013 surgery. Defendants supported their motion with extracts of Lyles' medical record and bill, the deposition testimonies of Drs. Sin and Zhang, and a declaration from Dr. Sin. In support of their motion, Defendants proposed as Statement of Fact No. 8:

> The LSU Health Sciences Shreveport implant record lists use of the three grafts which constitute the strut and two end plates of the cage; the Alantis Translational Plate; the screws that hold it in place; and Progenix. Exhibit 1, p. 30; Exhibit 2, pp. 70-71.

[Doc. No. 46, ¶8].

On November 3, 2015, Lyles filed an opposition memorandum to the Motion for Partial Summary Judgment. [Doc. No. 48]. In that memorandum, Lyles pointed to deposition testimony from Dr. Zhang and Dr. Sin about the use of Infuse, as well as a LSUHSC billing record. Lyles disputed Defendants' Statement of Fact No. 8:

> Plaintiff disputes Defendants' Paragraph 8. There remains a genuine dispute of material fact as to whether or not the Infuse Device is one of the devices listed on the implant record page. Plaintiff requested from Defendants all information in their possession concerning the types of devices manufactured by them and implanted in Bryant Lyles. Defendants refused to answer this discovery request despite having been given the implant page containing the part numbers of the devices listed [by] LSU.

[Doc. No. 50, ¶ 8].

On November 17, 2015, Defendants filed a reply memorandum. [Doc. No. 51].

On November 19, 2015, Lyles moved for an extension of discovery deadlines. [Doc. No. 52].

On November 23, 2015, Magistrate Judge Kirk granted the motion. On the same date, Magistrate Judge Kirk denied Medtronic's original Motion to Dismiss [Doc. No. 9] as moot. [Doc. No. 55]. Finally, that same date, Magistrate Judge Kirk issued a Report and Recommendation [Doc. No. 56] recommending that the Court grant Medtronic's Motion to Dismiss the Third Amended Complaint [Doc. No. 32] and that all claims against Medtronic be dismissed as prescribed. Additionally and, alternatively, Magistrate Judge Kirk found that the LUPTA and fraud claims against Medtronic based on Infuse were barred by the exclusivity provision of the LPLA.

Magistrate Judge Kirk further recommended that MSD's Motion to Dismiss the Third Amended Complaint [Doc. No. 31] be granted in part and denied in part. Magistrate Judge Kirk found that Lyles had set forth factual allegations sufficient to support his LPLA claim that the Atlantis Plate was defective in its construction or composition and to this extent recommended denial of the motion to dismiss. Magistrate Judge Kirk found Lyles' claims that the LUPTA and fraud claims against MSD based on Infuse were barred by the exclusivity provision of the LPLA and recommended that MSD's Motion to Dismiss be granted. Magistrate Judge Kirk found that Lyles had not set forth factual allegations sufficient to support his LPLA claim that the Atlantis Plate was defective in design because he failed to assert that an alternative design for the product, capable of preventing his damage, existed at the time the Atlantis Plate left MSD's control. However, Magistrate Judge Kirk recommended that the Court give Lyles leave to amend his Complaint a fourth time to properly assert this claim. Finally, Magistrate Judge Kirk found that Lyles had failed to state an LPLA claim for failure to warn with regard to Infuse, but he recommended that this claim be

dismissed without providing Lyles an opportunity to amend because such a claim would be expressly and/or impliedly preempted by the MDA, which amended the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq*.

On November 25, 2015, Defendants moved Magistrate Judge Kirk to reconsider his order granting certain discovery extensions. The Defendants argued that the deadlines had passed prior to the filing of the motion and that the granting of these extensions would have the effect of upsetting the trial date. Lyles responded to the motion for reconsideration, arguing that the pending motions to dismiss placed his counsel "in the lurch regarding which parties to depose and which experts . . . to obtain." [Doc. No. 60, p. 2]. Lyles also pointed out that he had already agreed to an extension of Defendants' expert report deadline. Finally, he denied that the extension would affect trial.

On December 8, 2015, Lyles filed objections to the Report and Recommendation. [Doc. No. 61].

On December 9, 2015, Magistrate Judge Kirk granted Defendants' Motion for Reconsideration. [Doc. No. 62]. He asked the Clerk of Court to place the motion on his calendar for consideration after full briefing.

On December 16, 2015, after the retirement of Magistrate Judge Kirk, the case was reassigned to Magistrate Judge Joseph Perez-Montes. The same day, MSD filed a Motion to Compel Lyles' Deposition. [Doc. No. 64]. Lyles opposed the motion. [Doc. No. 66]. On December 18, 2015, Magistrate Judge Perez-Montes granted the motion and ordered that Lyles give his discovery deposition on a mutually convenient date for counsel on or before January 8, 2016. [Doc. No. 67].

On December 22, 2015, MSD filed a response to Lyles' Objections to the Report and Recommendation. [Doc. No. 69].

On December 31, 2015, MSD filed a memorandum in opposition to Lyles' Motion for Extension of the Discovery Deadlines.

On December 31, 2015, the Court granted Lyles' motion for leave to file a reply in support of his objections to the Report and Recommendation. [Doc. Nos. 72 & 73].

On January 6, 2016, Lyles filed a reply in support of his Motion for Extension of the Discovery Deadlines. [Doc. No. 74]. On that same date, MSD filed a motion to expedite and motion for extension of time to file dispositive motions, which this Court granted on January 7, 2016. [Doc. No. 76].

On January 18, 2016, counsel for Medtronic/MSD deposed Lyles' expert, Dr. Walter Stringer. Dr. Stringer testified that a Verte-Stack vertebral body replacement had been used in Lyles' surgery along with the Progenix bone graft, that the Verte-Stack was still in place and had not migrated, and that it was not disturbed. [Doc. No. 109, Exh. 3, pp. 38, 44, 66 & 70].

On January 20, 2016, this Court issued a Ruling [Doc. No. 77] in which it adopted Magistrate Judge Kirk's Report and Recommendations on Medtronic's Motion to Dismiss the Third Amended Complaint [Doc. No. 32] and MSD's Motion to Dismiss the Third Amended Complaint [Doc. No. 31]. The Court issued the Ruling for additional, limited purposes of clarifying and supplementing the Report and Recommendation and addressing arguments raised for the first time in the objections. With regard to Medtronic's Motion to Dismiss the Third Amended Complaint [Doc. No. 32], the Court found that the claims against it were prescribed and, alternatively, were barred by the exclusivity provision of the LPLA. The Court granted in part and denied in part MSD's Motion to Dismiss the Third Amended Complaint [Doc. No. 31]. To the extent that MSD moved the Court to take judicial notice of FDA documents attached as Exhibits 1-6, the motion was granted. Further,

to the extent that MSD moved for dismissal of the fraud and LUPTA claims against it, the motion was also granted. To the extent that MSD moved for dismissal of Lyles' claim under the LPLA that the Atlantis Plate was defectively constructed or composed, the motion was denied. To the extent that MSD moved for dismissal of Lyles' claim under the LPLA that the Atlantis Plate was defectively designed, the motion was denied at that time, and Lyles was granted fourteen (14) days from the date of the Ruling to amend his Third Amended Complaint to properly allege a design defect claim. Lyles was cautioned that if he failed to amend to properly allege a design defect claim, that claim would also be dismissed with prejudice. [Doc. Nos. 77 & 78]. This Ruling effectively resolved Lyles' Infuse claims and left only the Atlantis Plate claims remaining for trial.

Also on January 20, 2016, the Court denied as moot Defendants' Motion for Partial Summary Judgment [Doc. No. 45] regarding Lyles' Infuse claims.

On January 25, 2016, MSD filed a Motion for Summary Judgment [Doc. No. 80] on Lyles' Atlantis Plate claims. On February 15, 2016, Lyles timely filed an opposition memorandum. [Doc. No. 83].

On February 18, 2016, Magistrate Judge Perez-Montes filed a Memorandum Order [Doc. No. 86] denying Lyles' motion for an extension of the discovery deadlines. He found that Lyles' "motion to extend discovery deadlines is untimely in part, he has not explained the delay in filing his motion, and he has not explained why he has been unable to complete discovery on time." *Id.* Therefore, Magistrate Judge Perez-Montes found that Lyles "has made no showing of good cause under Rule 16 . . . . that the existing deadlines could not be met with the exercise of due diligence." *Id.*

On February 24, 2016, Lyles filed a Motion *in Limine* [Doc. No. 87] to prevent MSD from introducing at trial evidence which was allegedly obtained in violation of his patient-healthcare

provider privilege.

On February 29, 2016, the parties jointly filed a proposed pre-trial order [Doc. No. 89] identifying MSD as the manufacturer of the Atlantis Plate. The parties stipulated that, during the May 10, 2013 surgery, "Dr. Sin inserted a Verte-Stack implant, a vertebral body replacement device . . . and also inserted Progenix, a putty-like bone graft material. . . . ." [Doc. No. 89, Stipulation No. 6].

Also on February 29, 2016, MSD filed a reply in support of its pending Motion for Summary Judgment [Doc. No. 90] and an opposition to Lyles' Motion *in Limine*. [Doc. No. 91].

On March 2, 2016, Lyles filed a reply in support of its Motion *in Limine*. [Doc. No. 94].

On March 8, 2016, Magistrate Judge Perez-Montes conducted a telephone pre-trial conference.

On March 16, 2016, after having been informed that an issue had arisen regarding MSD's expert, the Court held a telephone conference with counsel. [Doc. No. 96]. At the conference, the Court resolved an issue regarding Dr. Matthews, MSD's expert, and two other issues raised by MSD. [Doc. No. 97]. Lyles did not raise any other issues with the Court.

On March 23, 2016, the Court granted MSD's Motion for Summary Judgment [Doc. Nos. 98 & 99] and dismissed Lyles' remaining claims of defective construction and design of the Atlantis Plate. Lyles admitted that he lacked proof of an alternative design, so summary judgment on his design defect claim was granted on this basis. On his defective construction claim, the Court found that Lyles was unable to meet his evidentiary burden based on the testimony of his expert, Dr. W. Lynn Stringer ("Stringer"), or by reliance on the doctrine of *res ipsa loquitor*.

On April 4, 2016, Lyles filed a Motion for Reconsideration [Doc. No. 101], which was

opposed [Doc. No. 103]. After briefing was complete, the Court denied this motion as well. [Doc. No. 105].

Lyles appealed to the United States Court of Appeals for the Fifth Circuit on May 4, 2016. [Doc. No. 106].

On May 26, 2016, Lyles filed the instant Motion for Relief from Judgment. [Doc. No. 107]. MSD filed an opposition memorandum [Doc. No. 109]. Lyles filed a reply memorandum. [Doc. No. 112]. MSD filed a sur-reply memorandum [Doc. No. 116]. Lyles filed a sur-sur-reply memorandum [Doc. No. 114]. Finally, Lyles filed a sur-sur-sur reply memorandum. [Doc. No. 119].

Oral argument was held in open court on August 24, 2016.

MSD filed a post-argument memorandum. [Doc. No. 121]. Lyles filed a post-argument memorandum in response to that filed by MSD. [Doc. No. 122].

II. LAW AND ANALYSIS

A. Rule 60

Lyles asserts that, pursuant to Federal Rule of Civil Procedure 60(b), the Court should vacate its dismissal of this lawsuit and re-open the case to permit him to pursue additional LPLA claims against MSD and/or Medtronic because of newly discovered evidence regarding the Verte-Stack and/or alleged fraud or misconduct by MSD and /or Medtronic in discovery.

Rule 60(b) states, in pertinent part:

> On motion and just terms, the court may relieve a party . . . from final judgment, order, or proceeding for the following reasons: . . . (2) newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b); (3) fraud (whether previously called intrinsic or extrinsic), misrepresentation, or misconduct by an opposing party . . . .

1. New Evidence

Lyles first argues that the Court should grant him relief from judgment based on the new evidence he has obtained regarding the use of Verte-Stack and Progenix in a cervical surgery.

Motions for relief from judgment are "extraordinary," and the requirements of Rule 60 must be "strictly met." *Longden v. Sunderman*, 979 F.2d 1095, 1102 (5th Cir.1992). Relief from final judgment under Rule 60(b)(2) is only appropriate when the movant discovers new evidence "that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b)." FED. R. CIV. PROC. 60(b)(2). Further, to succeed on a motion for relief from judgment based on newly discovered evidence, the "movant must demonstrate: (1) that it exercised due diligence in obtaining the information; **and** (2) that the evidence is material and controlling and clearly would have produced a different result if present before the original judgment." *Hesling v. CSX Transp., Inc.*, 396 F.3d 632, 639 (5th Cir. 2005) (emphasis added) (internal citations and quotations omitted).

Lyles asserts that on May 10, 2016, an anonymous caller alerted Lyles' counsel that MSD had not provided "full responses to discovery with regard to the Verte-Stack" used in Lyles' surgery. [Doc. No. 107-1, p. 1]. This unknown caller provided Lyles' counsel with a manual for the Verte-Stack revealing that the device is allegedly contraindicated for use in the cervical spine, contraindicated for use with the Atlantis Plate, and not designed for use with the "biologics," including Progenix, listed in his medical chart. *Id.* Lyles' counsel then did further research and found the FDA 510(k) clearance summary published in 2007 for the Verte-Stack which allegedly "indicates [MSD] made changes to the original device design in order to make it smaller and, therefore capable of use in the cervical spine." *Id.* at pp. 1-2. Lyles' counsel found that the

Verte-Stack cage component sizes listed in his medical chart of 11 mm, 5 mm, and 11mm, are not consistent with MSD's publicly available literature for Verte-Stack which indicates that the smallest component size available is 12 mm.

Lyles argues that (1) all of this evidence was available prior to the Court's granting of summary judgment to MSD, (2) he exercised due diligence by issuing discovery requests to MSD/Medtronic that should have resulted in the provision of information on these products, (3) the new evidence is material, and (4) if he had the evidence prior to dismissal of the case, he could have moved to amend his complaint a fourth time to add failure to warn and design defect claims against MSD/Medtronic based on the use of the Verte-Stack in the anterior cervical surgery and the accompanying use of Progenix.

MSD responds that Lyles was aware that the Verte-Stack and Progenix were used in his May 13, 2015 surgery, well before the Court granted summary judgment on March 23, 2016. If, as Lyles asserts, he requested documentation on Verte-Stack and Progenix in his May 28, 2015 Request for Production No. 5 and Interrogatory No. 2, he never took any steps to object to MSD's failure to provide documentation or information–i.e., he never made any further requests nor did he file a motion to compel. Under these facts and circumstances, MSD argues that the evidence is not newly discovered and does not provide a basis for relief from judgment.

The Court agrees with MSD. From the time Lyles began pursuing a malpractice claim against Dr. Sin and at the time he filed this lawsuit, Lyles' focus was on the Atlantis Plate. Later, he also pursued a claim based on the alleged use of Infuse. However, at no time did Lyles indicate that he was attempting to pursue an LPLA claim based on the use of Verte-Stack and/or Progenix. While it is not clear exactly when Lyles' counsel received his medical records, they were received

some time in January or February 2015. The May 10, 2013 Implant Log clearly identified the use of Progenix, although it did not list the name of the manufacturer. On the other hand, the Implant Log referred to an anatomical implant manufactured by "Medtronic," but did not identify that product by name as the Verte-Stack. Nevertheless, no later than the end of May 2015, Lyles had received a copy of Dr. Mathews' report which stated that the Verte-Stack was used in his May 10, 2013 surgery. Throughout this litigation, the two products were identified numerous other times. By August 17, 2015, when the depositions of Dr. Sin and Dr. Zhang were held, it was clear that these products were both used and that both products were manufactured by Medtronic or MSD. Yet, Lyles never made any discovery requests specifically for information or documentation related to these products.

Lyles asserts that his Request for Production No. 5 and Interrogatory No. 2 in his May 28, 2015 discovery requests should have resulted in MSD's provisions of information on the Verte-Stack and Progenix, even though no claims were made against MSD or Medtronic based on these products in any of his four complaints (the Complaint, the Amended Complaint, the Second Amended Complaint and the Third Amended Complaint). Even if the Court accepts that Lyles intended to elicit information on products other than the Atlantis Plate and Infuse, MSD responded to these discovery requests in September 2015, pointed to the Implant Log as listing the device or products it manufactured, but did not provide any documents on the Verte-Stack or Progenix and did not make any objection to providing these documents. It is the Court's belief, based on the statements of counsel at oral argument and the record in this case, that MSD's counsel did not consider the requests as pertaining to any products other than the Atlantis Plate and Infuse. Although the request was broadly worded, it was not unreasonable for counsel to interpret the request as limited to the two

products about which the parties were in dispute.

Further, even if Lyles' discovery requests were designed to elicit documentation on the Verte-Stack and Progenix, then his actions following the receipt of MSD's September 2015 discovery responses do not constitute due diligence. Lyles did not make any further inquiry through counsel as to why MSD failed to produce documentation or make an objection to the production of such evidence, nor did he file a motion to compel. Under these facts and circumstances where Lyles and his counsel knew about the products,[3] knew they were used in his surgery, and knew they were manufactured by MSD or Medtronic, the Court finds that Lyles did not exercise due diligence to obtain discovery of the very facts that he easily obtained after the anonymous call. Thus, Lyles' Motion for Relief from Judgment is denied on this basis.

2. Fraud

Lyles also contends that his motion should be granted because MSD fraudulently failed to disclose information about Verte-Stack and Progenix. In addition to the discovery requests made to MSD, Lyles points to a pending *qui tam* action in California against Medtronic, MSD, and related entities regarding the use of the Verte-Stack in similar surgeries, including at least one claim in Louisiana.

"A party making a Rule 60(b)(3) motion must establish (1) that the adverse party engaged in fraud or other misconduct, and (2) that this misconduct prevented the moving party from fully and fairly presenting his case." *Hesling*, 396 F.3d at 641 (internal citations omitted). "The moving party

[3]Counsel also argues that the device was identified as a "Verte-Stack Anatomic PEEK" by surgeons, but is called a "Verte-Stack Spinal System" in Medtronic/MSD's literature. [Doc. No. 107-1, p. 10 n.13]. Counsel explains that this difference in terminology affected their ability to conduct internet searches. While the Court does not doubt counsel's sincerity, this issue would have been resolved by their exercise of due diligence in the discovery process.

has the burden of proving the misconduct by clear and convincing evidence." *Id*. (internal citations omitted). "Unlike Rule 60(b)(2), 60(b)(3) does not require that the information withheld be such that it can alter the outcome of the case." *Id*. (internal citations omitted). "Rule 60(b)(3) is aimed at judgments which were unfairly obtained, not at those which are factually incorrect." *Id*. (internal citations and quotations omitted).

In this case, Lyles failed to present the Court with evidence that MSD or its counsel engaged in any misconduct at all. Lyles has done no more than speculate that MSD and its counsel were aware of issues with Verte-Stack and Progrenix and, therefore, intentionally failed to disclose information about those products.[4] Lyles' suggestion that MSD and/or Medtronic must have known about and concealed the existence of the *qui tam* action of California is without merit. A review of the docket sheet available for public access shows that, as with any *qui tam* or False Claims Act case, the lawsuit was originally filed under seal and was not served on any Medtronic or MSD entity until July 2016, after this lawsuit was dismissed.[5] Thus, Lyles' Motion for Relief from Judgment is also denied on this basis.

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[4]Lyles also points to the testimony of Medtronic and MSD's expert, Dr. Mathews, as evidence of fraud. As vice-president of medical affairs and clinical affairs for Medtronic between 2007 and 2011, Dr. Mathews was involved in the pre-market approval for spine products. Because Verte-Stack was approved by the FDA in 2007, Lyles speculates that Dr. Mathews must have known all the information contained in the literature and testified fraudulently that Lyles' surgeons used an appropriate standard of care. However, it is just as likely that the process for obtaining pre-market approval took place before Dr. Mathews' employment began. Lyles has not produced clear and convincing evidence of any deceit by Dr. Mathews. Further, Lyles has produced no evidence that MSD and Metronic's counsel were aware of and actively concealed information on Verte-Stack and Progenix.

[5]The lawsuit remained sealed until both the United States and the named states in which patients were located declined intervention. The case is now being pursued by the individual Plaintiff "The Dan Abrams Company, LLC." *See United States of America ex. rel. v. Medtronic, Inc., et al.*, Docket No. 2:15-cv-01212-JAK-AS (C.D. Ca.) [Doc. Nos. 18, 19 & 24].

III. CONCLUSION

For the foregoing reasons, Lyles' Motion for Relief from Judgment [Doc. No. 107] is DENIED.

MONROE, LOUISIANA, this 31st day of August, 2016.

ROBERT G. JAMES
UNITED STATES DISTRICT JUDGE